K070002

510(k) Summary for the Boston Scientific PICC

A. Sponsor

Boston Scientific/ Oncology Division
100 Boston Scientific Way
Marlborough, MA 01756

AUG 17 2007

B. Contact

Nicholas Condakes
Manager, Regulatory Affairs
508-683-4003
or
Lorraine M. Hanley
Director, Global Regulatory Affairs
508-683-4173

C. Device Name

Tradename:	To be determined
Common/usual name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	LJS - Long term intravascular catheter 21 CFR 880.5970, Class II

D. Predicate Device(s)

Tradename:	Morpheus™ CT PICC
Common/usual name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	LJS- Long term intravascular catheter 21 CFR 880.5970, Class II
Premarket Notification:	AngioDynamics, Inc. Morpheus™ CT PICC, K041420 and K060887

E. Device Description

The proposed PICC is designed for intravenous therapy and for use with power injectors at settings of 300 psi for the administration of contrast media for imaging studies (including, but not limited to, CT scans, MRIs). The proposed PICC is an open ended, non-valved catheter with proximally located luer lock hub(s), extension tube(s) and suture wing for catheter securement; available in single and dual lumen configurations (4 Fr SL, 5 Fr SL, 5 Fr DL, 6 Fr DL); with a reverse tapered shaft to aid in staunching bleeding at the insertion site; and usable length of 45 cm lengths for the 4 Fr SL, 5 Fr DL lengths and 55 cm lengths for the 4 Fr SL, 5 Fr SL, 5 Fr DL, 6 Fr DL. The radiopaque catheter is marked with depth indicators every 1 cm along its length and with a "0" indicator to serve as a reference during catheter insertion and for user convenience in catheter sizing. The lumens are differentiated by proximally located colored clamps and hubs that indicate lumen size. Maximum power injection flow rates are indicated on the clamp(s). As is the predicate device, the proposed BSC PICC will be offered in convenience kits with other legally marketed products.

F. Intended Use

The proposed device is indicated for short or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to the administration of fluids, medications and nutrients; the sampling of blood; and for power injection of contrast media.

G. Substantial Equivalence

Utilizing FDA's Guidance for Industry and FDA staff Format for Traditional and Abbreviated 510(k)s a direct comparison of key characteristics demonstrates that the proposed device is substantially equivalent to the predicate device in terms of intended use, technological characteristics, and performance characteristics tested.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 2007

Mr. Nicholas Condakes
Manager, Regulatory Affairs
Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K070002
Trade/Device Name: Boston Scientific Peripherally Inserted Central Catheter
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: July 26, 2007
Received: July 272007

Dear Mr. Condakes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if Known): K070002

Device Name: Undetermined

Indications For Use:

The proposed Boston Scientific power injectable PICC is indicated for short or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to the administration of fluids, medications and nutrients; the sampling of blood; and for power injection of contrast media.

Prescription Use __X____ **AND/OR** **Over-The-Counter Use**_____
(21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K070002